



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0540; FRL-9920-54]

Fosetyl-Al; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of Aluminum tris (*O*-ethylphosphonate) (fosetyl-Al) in or on pepper/eggplant, subgroup 8-10B. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0540, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202)

566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfrNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To

access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0540 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0540, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of November 7, 2014 (79 FR 66347) (FRL-9918-69), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E8182) by Bayer CropScience, 2 T.W. Alexander Dr., P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.415 be amended by establishing tolerances for residues of the fungicide fosetyl-Al, aluminum tris (*O*-ethylphosphonate), in or on pepper/eggplant, subgroup 8-10B at 0.01 parts per million (ppm) and non-bell (chili) pepper, dried fruit at 0.01 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is not establishing a separate tolerance for residues of fosetyl-Al on pepper, non-bell (chili), dry fruit. The reason for this is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fosetyl-Al including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fosetyl-Al follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The major target organs following repeated oral exposure to fosetyl-Al are the reproductive system in the dog (testicular degeneration: Spermatocytic and/or spermatidic giant cells in the lumen of the seminiferous tubules) and the urinary system in the rat (histopathological changes in the kidney, impairment of calcium/phosphorus metabolism, calculi and hyperplasia in the urinary tract, bladder tumors). There is no concern for increased quantitative or qualitative susceptibility of the young following *in utero* (rats and rabbits) and pre-and postnatal exposure (rats) to fosetyl-Al. Also, there is no evidence of developmental toxicity, reproductive toxicity in the rat, neurotoxicity, or immunotoxicity at dose levels that do not exceed the limit dose. The microscopic finding in the dog testes may be considered an isolated finding in light of the lack of any functional deficits in the rat 2-generation reproductive toxicity study and the lack of effects on the rat reproductive organs following chronic exposure. Additionally, a clear no-observed-adverse-effect level (NOAEL) was established for the effect observed in the dog and was selected as a suitable point of departure (POD) for the chronic dietary (all populations) exposure scenario. Fosetyl-Al is negative for carcinogenicity except at extremely high doses (>limit dose) in rats and mice, and it did not show any genotoxic potential (classified as not likely to be carcinogenic to humans). Fosetyl-Al is not acutely toxic via the oral, dermal, and inhalation routes. It produces severe eye irritation, is not a dermal irritant, and is negative for dermal sensitization.

Specific information on the studies received and the nature of the adverse effects caused by fosetyl-Al as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Fosetyl-Aluminum [Fosetyl-Al]: Human Health Risk Assessment for the

Establishment of Tolerances with No U.S. Registration in/on Pepper/eggplant, Subgroup 8-10B and Pepper, Non-bell (Chili), Dry Fruit” in docket ID number EPA-HQ-OPP-2014-0540.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level -- generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fosetyl-Al used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Fosetyl-Al for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	No hazard or appropriate acute endpoint was identified in the database.		
Chronic dietary (All populations)	NOAEL= 250 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 2.5 mg/kg/day cPAD = 2.5 mg/kg/day	Chronic oral toxicity (dog) LOAEL = 500 mg/kg/day based on increased incidence of testicular degeneration (spermatocytic and/or spermatidic giant cells in the lumen of the seminiferous tubules)
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months)	NOAEL= 300 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE < 100	3-generation reproduction (rat) LOAEL = 600 mg/kg/day based on decreased body weight gains in the F2b generation and urinary tract changes in adults
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Inhalation (or oral) study NOAEL= 300 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE < 100	3-generation reproduction (rat) LOAEL = 600 mg/kg/day based on decreased body weight gains in the F2b generation and urinary tract changes in adults
Cancer (Oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fosetyl-Al, EPA considered exposure under the petitioned-for tolerances as well as all existing fosetyl-Al tolerances in 40 CFR 180.415. EPA assessed dietary exposures from fosetyl-Al in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for fosetyl-Al; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA's unrefined chronic analysis is based on tolerance-level residues and 100% crop treated (PCT) assumptions. Default processing factors were used for all crops except for citrus where processing studies showed no residue concentration; thus, the processing factor was set to one for processed citrus commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fosetyl-Al is not carcinogenic to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for fosetyl-Al. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fosetyl-Al in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fosetyl-Al. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Environmental fate properties suggest that fosetyl-Al is not likely to reach ground or surface water under most conditions, and if it does reach surface water, it is expected to degrade rapidly. Using the Screening Concentration in Ground Water (SCI-GROW) model, the estimated drinking water concentration (EDWC) of fosetyl-Al for chronic exposures for non-cancer assessments is estimated to be 0.006 parts per billion (ppb) for ground water. Thus, the ground water EDWC of 0.006 ppb was directly incorporating into the chronic dietary risk assessment.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fosetyl-Al is currently registered for the following use that could result in residential exposure: turf. EPA assessed residential exposure using the following assumptions: residential handler and residential post-application exposures. The residential handler assessment quantitatively evaluated inhalation exposure from hose end sprayer for turf applications but not dermal exposure as no dermal point of departure was identified. There is the potential for short-term post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with fosetyl-Al

(based on contact with treated turf at the maximum turf application rate of 17.6 pounds (lbs) active ingredient/Acre (ai/A)). Incidental oral post-application exposure is quantitatively assessed for children 1 to <2 years old for exposure to treated turf. Dermal post-application exposure was not assessed because no dermal hazard was identified. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Although fosetyl-Al shares a similar chemical structure with many organophosphates (OPs), there is no evidence of neurotoxicity or evidence of cholinesterase inhibition following exposure to fosetyl-Al at dose levels at and greater than the limit dose. EPA has concluded that fosetyl-Al is a not member of the OP cumulative group. EPA has not found fosetyl-Al to share a common mechanism of toxicity with any other substances either, and fosetyl-Al does not appear to produce a toxic metabolite produced by any other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fosetyl-Al does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative

effects of such chemicals, see EPA's website at

<http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility following *in utero* exposure to fosetyl-Al in either the rat (at dose levels that do not exceed the limit dose) or rabbit developmental toxicity study, and there is no evidence of increased susceptibility following *in utero* and/or pre-/ postnatal exposure in the 3-generation reproduction study in rats.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for fosetyl-Al is complete.

ii. There is no indication that fosetyl-Al is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that fosetyl-Al results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 3-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the water modeling used to assess exposure to fosetyl-Al in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fosetyl-Al.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse

effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fosetyl-Al is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fosetyl-Al from food and water will utilize 12% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fosetyl-Al is not expected.

3. *Short-term risk.* Fosetyl-Al is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fosetyl-Al.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 3,200 for adult residential handlers applying liquid concentrates to turf via hose-end sprayer and for children, 540 for children's incidental oral post-application exposure from contacting treated lawns. Because EPA's level of concern for fosetyl-Al is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Because no intermediate-term non-occupational exposures are expected, fosetyl-Al is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A, fosetyl-Al is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fosetyl-Al residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Rhone-Poulenc Method No. AR 154-97 underwent successfully independent laboratory validation for use as an enforcement analytical method. Although the tolerance expression includes only parent fosetyl-Al, Method AR 154-97 was validated for both fosetyl-Al and its metabolite, phosphorous acid.

In support of the pepper trials, the registrant made use of a data collection method, Method No. 00861/M001, which achieved a lower Limit of Quantitation (LOQ) than Method AR 154-97. Method No. 00861/M001 is an HPLC-MS/MS (high performance liquid chromatography–tandem mass spectrometry) method that uses the same extraction solvent as Method AR 154-97. Sufficient method validation data were submitted with the field trial data to support a LOQ of 0.01 ppm for fosetyl-Al residues in pepper (bell and non-bell). As EPA encourages the development of improved analytical methods and because both methods use the same extraction solvent, EPA considers Method No. 00861/M001 to also be a suitable enforcement method for peppers. Thus, both methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for fosetyl-Al.

C. Response to Comments

The Agency received a comment expressing concerns about allowing residues of pesticides on eggplant and peppers. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed because of potential effects. However, under the existing legal framework provided by FFDCA section 408, EPA is authorized to establish pesticide tolerances where persons seeking such tolerances have demonstrated that the pesticide meets the safety standard imposed by the statute. Based on its assessment of the available data, the Agency has concluded there is a reasonable certainty that no harm will result from aggregate exposure to residues of fosetyl-Al.

D. Revisions to Petitioned-For Tolerances

EPA is not establishing a separate tolerance for residues of fosetyl-Al in or on pepper, non-bell (chili), dry fruit. The residues found on the dried commodity will be covered by the tolerance for residues of fosetyl-Al in or on pepper/eggplant, subgroup 8-10B; therefore, no separate tolerance is needed.

V. Conclusion

Therefore, tolerances are established for residues of fosetyl-Al, aluminum tris (*O*-ethylphosphonate), in or on pepper/eggplant, subgroup 8-10B at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the

issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to

publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 23, 2014.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.415, add alphabetically “Pepper/eggplant, subgroup 8-10” to the table in paragraph (a) to read as follows:

§ 180.415 Aluminum tris (*O*-ethylphosphonate); tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * *	* * *
Pepper/eggplant, subgroup 8-10B ¹	0.01
* * * *	* * *

¹ There are no US registrations as of December 23, 2014.

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